

A Case Control Etiologic Study of Sarcoidosis

Confirmation of Eligibility (Cases)

ID No.				-				
Form Type	C	A	0	1				

INSTRUCTION: ABSTRACT QUESTIONS 1 AND 4 FROM PARTICIPANT INFORMATION FORM (FORM 01). IF AT ANY TIME, THE RESPONSE TO A QUESTION IS A STOP CONDITION, DO NOT COMPLETE THIS FORM.

1. CASE'S INITIALS: _____

2. DATE OF CONFIRMATION OF ELIGIBILITY: _____ - _____ - _____ f02_dy
Month Day Year

3. HAS THE CASE AGREED TO BE IN THIS STUDY? Yes (1) No (STOP) agr_stdy

4. CASE'S GENDER: (1) (2) gender
Male Female

5. What is your age? _____ age

A. CASE IS LESS THAN 18 YEARS OLD Yes (STOP) No (2) lt_18yr

6. Do you consider yourself:
INTERVIEWER READ LIST race

White	(1)
Black or African American	(2)
Asian/Pacific Islander	(3)
American Indian or Alaska Native	(4)
Other	(5)

Specify: _____

- | | | | |
|----------------------|-------|-------|----------|
| | Yes | No | |
| 7. Are you Hispanic? | (1) | (2) | hispanic |
-
- | | | | |
|---|-----|----|--|
| | Yes | No | |
| 8. DID THE CASE MEET ANY OF THE FOLLOWING EXCLUSION CRITERIA. INTERVIEWER ASK EACH QUESTION. | | | |
- | | | | |
|---|--------|-------|-----------|
| A. Has a doctor told you that you now have active tuberculosis or are you now taking any medication for tuberculosis? | (STOP) | (2) | tbrcm |
| B. Has a doctor ever told you that you had tissue diagnosis of sarcoidosis more than six months prior to today? | (STOP) | (2) | sarc_gt6 |
| C. Has a doctor ever told you that you have primary biliary cirrhosis? | (STOP) | (2) | pr_bicir |
| D. Has a doctor ever told you that you have Crohn's disease? | (STOP) | (2) | chrandi |
| E. Have you ever had medication for histoplasmosis or other fungal infections of your lungs? | (STOP) | (2) | histopl m |
| F. Has a doctor ever told you that you have chronic beryllium disease? | (STOP) | (2) | beryl di |

INSTRUCTION: THE REMAINDER OF THESE QUESTIONS ARE NOT ASKED OF THE CASE.

- | | | | |
|--|-------|--------|----------|
| | Yes | No | |
| 9. HAS TISSUE SPECIMEN BEEN OBTAINED FOR DIAGNOSIS? | (1) | (STOP) | spec_obt |
- | | | | |
|-----------------------------------|-------|-----|------|
| A. IF YES, DATE OF BIOPSY: | | | |
| _____ - _____ - _____ | Month | Day | Year |

(Date of biopsy must be six months or less prior to enrollment.)

10. WHERE WERE THE DIAGNOSTIC BIOPSIES PERFORMED?

	ACCESS Clinical Center	Other Medical Center	Not Done	
A. BRONCHOSCOPY	(1)	(2)	(3)	bronperf
B. LYMPH NODE	(1)	(2)	(3)	lympperf
C. SKIN	(1)	(2)	(3)	skinperf
D. KVEIM/OTHER	(1)	(2)	(3)	othperf

Specify: _____

REMINDER: REQUEST PATHOLOGICAL REVIEW OF THE SPECIMEN FOR MYCOBACTERIA AND FUNGI.

11. HAS PATHOLOGY REPORT (ACCESS FORM 31) BEEN COMPLETED?

Yes No
(1) (2) pathcomp

IF NO, GO TO QUESTION 14.

A. DATE OF REPORT:

_____ - _____ - _____ path_dy
Month Day Year

B. TISSUE PATHOLOGY REPORT CONCERNING THE PRESENCE OF NONCASEATING GRANULOMA(S) CONSISTENT WITH THE DIAGNOSIS OF SARCOIDOSIS.

Definitely positive (1) dia_sarc
Probable (2)
Possible (3)
Definitely negative (STOP)

C. ANY PATHOLOGY EXCLUSION (HISTOPLASMOSIS, TUBERCULOSIS, FUNGAL).

Yes No
(STOP) (2) path_exc

IF PATHOLOGY REPORT INDICATES PROBABLE OR POSSIBLE DIAGNOSIS OF SARCOIDOSIS, SUBMIT TISSUE SPECIMEN TO TISSUE SAMPLE READING PROGRAM. COMPLETE FORM 40, TISSUE SAMPLE SHIPPING FORM.

12. WERE SPECIMENS SENT FOR CULTURE?
- | | (1)
Acid Fast
Bacilli | | (2)
Fungus | | (3)
Other | |
|---------------------------------|-----------------------------|-----|-----------------|-----|----------------|-----|
| | Yes | No | Yes | No | Yes | No |
| A. LUNG BIOPSY | (1)
lungacid | (2) | (1)
lungfung | (2) | (1)
lungoth | (2) |
| B. LYMPH NODE | (1)
lympacid | (2) | (1)
lympfung | (2) | (1)
lympoth | (2) |
| C. BRONCHIAL LAVAGE OR WASHINGS | (1)
bronacid | (2) | (1)
bronfung | (2) | (1)
bronoth | (2) |
| D. OTHER | (1)
othacid | (2) | (1)
othfung | (2) | (1)
othoth | (2) |

Specify: _____

13. WAS THE CULTURE POSITIVE FOR ACID FAST BACILLI, FUNGUS OR OTHER EXCLUDED INFECTIOUS AGENT IN ANY OF THE SPECIMENS?
- Yes No
(STOP) (2) cultpos
14. HAVE ANY STOP RESPONSES BEEN CHECKED?
- Yes No
(STOP) (2) stopresp

IF YES, CASE CANNOT BE REGISTERED.
IF NO, CASE CAN BE REGISTERED. COMPLETE ACCESS FORM 03 AND CALL ATRS.

15. Research Coordinator:

A. Signature: _____

B. ACCESS Staff No.: _____ - _____

16. Date form completed: _____ - _____ - _____
Month Day Year

FORM 02
Confirmation of Eligibility (Cases)

<u>ITEM</u>	<u>NAME</u>	<u>TYPE (LENGTH)</u>	<u>CODES OR UNITS</u>
	REV	I (1)	Form revision
	NEWID	F (5.1)	Patient ID
2	F02_DY	I (4)	Days from enrollment to Conf of Eligibility
3	AGR_STDY	I (1)	Case agreed to be in study 1=Yes 2=No
4	GENDER	I (1)	Gender 1=Male 2=Female
5	AGE	I (2)	Age (Years) 1= <30 2=30-39 3=40-49 4=50-59 5= >=60
5a	LT_18YRS	I (1)	Case is less than 18 1=Yes 2=No
6	RACE	I (1)	Race 1=White 2=Black or African American 3=Asian/Pacific Islander ⁺ 4=American Indian or Alaska Native ⁺ 5=Other ⁺
7 ⁺	HISPANIC	I (1)	Hispanic
8a	TBRM	I (1)	Active TB 1=Yes 2=No
8b	SARC_GT6	I (1)	Sarcoidosis > 6 mos 1=Yes 2=No
8c	PR_BICIR	I (1)	Had cirrhosis 1=Yes 2=No
8d	CROHNDI	I (1)	Had Crohn's disease 1=Yes 2=No
8e	HISTOPLM	I (1)	Meds for histoplasmosis 1=Yes 2=No
8f	BERYLDI	I (1)	Had chronic beryllium disease 1=Yes 2=No
9	SPEC_OBT	I (1)	Tissue specimen obtained 1=Yes 2=No
9a	BIOP_DY	I (4)	Days from enrollment to biopsy

⁺ Deleted for confidentiality

FORM 02
Confirmation of Eligibility (Cases)
(Continued)

<u>ITEM</u>	<u>NAME</u>	<u>TYPE (LENGTH)</u>	<u>CODES OR UNITS</u>
10a	BRONPERF	I (1)	Bronchoscopy performed where? 1=ACCESS Clinical Center 2=Other Medical Center 3=Not Done
10b	LYMPPERF	I (1)	Lymph Node biopsy perf where? 1=ACCESS Clinical Center 2=Other Medical Center 3=Not Done
10c	SKINPERF	I (1)	Skin biopsy performed where? 1=ACCESS Clinical Center 2=Other Medical Center 3=Not Done
10d	OTHPERF	I (1)	KVEIM/other biosy perf where? 1=ACCESS Clinical Center 2=Other Medical Center 3=Not Done
11 *	PATHCOMP	I (1)	Pathology report completed 1=Yes 2=No
11a	PATH_DY	I (4)	Days from enrollment to pathology report
11b	DIA_SARC	I (1)	Pathology report consistent 1=Definitely positive
11c	PATH_EXC	I (1)	Any pathology exclusion 1=Yes 2=No
12a1	LUNGACID	I (1)	Lung biopsy--acid fast bacilii 1=Yes 2=No
12a2	LUNGFUNG	I (1)	Lung biopsy--fungus 1=Yes 2=No
12a3	LUNGOTH	I (1)	Lung biopsy--other 1=Yes 2=No
12b1	LYMPACID	I (1)	Lymph Node--acid fast bacilii 1=Yes 2=No
12b2	LYMPFUNG	I (1)	Lymph Node--fungus 1=Yes 2=No

* Refer to the form for skip pattern for this item.

FORM 02
Confirmation of Eligibility (Cases)
(Continued)

<u>ITEM</u>	<u>NAME</u>	<u>TYPE (LENGTH)</u>	<u>CODES OR UNITS</u>
12b3	LYMPOTH	I (1)	Lymph Node--other 1=Yes 2=No
12c1	BRONACID	I (1)	Br Lavage--acid fast bacilii 1=Yes 2=No
12c2	BRONFUNG	I (1)	Br Lavage--fungus 1=Yes 2=No
12c3	BRONOTH	I (1)	Br Lavage--other 1=Yes 2=No
12d1	OTHACID	I (1)	Other--acid fast bacilii 1=Yes 2=No
12d2	OTHFUNG	I (1)	Other--fungus 1=Yes 2=No
12d3	OTHOTH	I (1)	Other--other 1=Yes 2=No
13	CULTPOS	I (1)	Culture was positive 1=Yes 2=No
14	STOPRESP	I (1)	Any stop responses 1=Yes 2=No